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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,763	10/12/2001	Joseph C. Trautman	ARC 2972 R1	2098

7590 07/18/2005

FRANCIS LAW GROUP  
1942 EMBARCADERO  
OAKLAND, CA 94606

EXAMINER
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NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tate

<b>Office Action Summary</b>	<b>Application No.</b> 09/976,763	<b>Applicant(s)</b> TRAUTMAN ET AL.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-23 are rejected.
- is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. In response to applicant's amendment of 05/09/2005, the examiner has removed all prior 35 USC § 112 rejections.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 17-23 are rejected under 35 U.S.C. 102 (b) as being anticipated by Boudjema (5,827,297).

Boudjema discloses in fig. 2, a device for impacting a penetrating member against the skin having the limitations as recited in the above listed claims, including: a body (17), a piston (18) slidably disposed within the body for impacting the penetrating member (20) against the skin, an impact spring (37) adapts to provide an impact force to the piston, where a locking mechanism (31) adapts to engage the piston with the body after the piston has been disposed within the body, where a releasing mechanism (36) is capable of disengaging the locking mechanism which includes releasably engaging lock members (27,28) on the body and piston, and where the impact spring impacts the piston (18) against the penetrating member forcing the penetrating member (20) into the skin. Further, the piston is capable of engaging a thin and flat member (20) to transmit the impact force to the thin and flat member, where a retainer (5) is adapted to releasably secure a thin and flat member.

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Note that the procedure in fig. 2 disclose an application surface (to the left side of element 16) can have a convexed shaped that is conform to a predetermined body surface site.

Regarding claims 7-10, 14-15 and 17, Boudjema discloses the device having the limitations as recited in the above listed claims, including a cap (element 19 is considered a cap) which is capable of movably mounted on the body for activating the releasing mechanism (36), where the releasing mechanism adapts to release the piston after a force is exerted upon the releasing mechanism, where the device further has a hold down spring (27) disposed between the body and the cap, where the hold down spring is capable of exerting a predetermined force, and where the device further has an indicator (29) for indicating when the cap is in the locked position, and where the piston (18) is from the cocked position to impact the skin with the microblade array (33) when the hold down spring is compressed. Regarding claims 18-22, Boudjema clearly teaches the method steps as claims in figure 2.

### *Response to Arguments*

3. Applicant's arguments filed 5/9/2005 have been considered but they are not persuasive. In response to applicant's argument that figure 2 of Boudjema does not include a piston that is configured to engage a thin and flat member and to transmit the impact force to the thin and flat member: As claim 1 is currently written, it can be interpreted broadly that the Boudjema reference at least discloses in fig. 2, a piston (18) is capable of engaging a thin and flat member (element 20 is considered as a thin and flat member) to transmit the impact force to the thin and flat member.

In response to applicant's argument regarding "a device for mechanically applying a penetrating member against a user's stratum corneum"; This is a functional limitation. Thus, a

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reference needs not show the structure of the recitation in order to meet the claim language but rather the reference needs only be capable of being used with such structure. Accordingly, the above noted reference is still considered to read on the claimed limitations of the claims noted.

Newly submitted claim 24 is directed to an invention that is dependent from non-elected invention for the following reasons: originally presented claims 1-15 and 17-22 were related to Species 1, for figs. 1-4(which was elected in 1/21/2004). While newly submitted claim 24 is directed to Species 2 of figs. 5-7, which is distinct from the originally claimed species. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively by original presentation for prosecution on the merits. Therefore, **claim 24 is withdrawn from consideration** as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### *Conclusion*

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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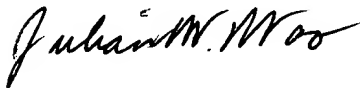
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen  
Examiner  
Art Unit 3731

Vn JP  
7/13/2005



**JULIAN W. WOO**  
**PRIMARY EXAMINER**